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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,912	03/05/2002	Richard R. Bott	GC724	9189

7590

01/26/2005

JANET KAISER CASTANEDA  
GENENCOR INTERNATIONAL, INC.  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304-1013

EXAMINER
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STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 10/091,912	<b>Applicant(s)</b> BOTT ET AL.	
	<b>Examiner</b> David J Steadman	<b>Art Unit</b> 1652	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 20 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,2,9,19 and 27-38.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

David J. Steadman, Ph.D.  
Primary Examiner  
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## **ADVISORY ACTION**

### ***Status of the Application***

**[1]** Applicants' amendment to the claims, filed December 20, 2004, is acknowledged and has been entered into the application. This listing of the claims replaces all prior versions and listings of the claims.

**[2]** The request for reconsideration of the claims is acknowledged, however, the amendment fails to place the claims in a condition for allowance for the reasons stated below.

**[3]** In order to clarify the record, it is noted that applicants' grouping of the claims as set forth at p. 6 of the response filed 12/20/2004 does not accurately reflect the grouping of the claims as set forth in the Office action mailed 11/18/2003.

**[4]** The objection to claims 2 and 29 under 37 CFR 1.75(c), as being of improper dependent form is maintained for the reasons of record.

RESPONSE TO ARGUMENT: Applicants argue claims 1 and 28 are broader than claims 2 and 29 in that claims 1 and 28 encompass cutinases obtained from organisms other than *P. mendocina*, while claims 2 and 29 limit the source of the cutinase variant.

Applicants' argument is not found persuasive. As stated in a previous Office action and undisputed by applicants, "[t]here is no indication in the specification that the polypeptide of claim 2, *i.e.*, the polypeptide of claim 1 isolated from *P. mendocina*, is any different from the polypeptide of claim 1." In other words, absent evidence to the contrary, the cutinase variant of claim 2 is no different than the cutinase of variant of

claim 1, regardless of its source. Similar reasoning applies to claims 28 and 29.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

**[5]** The written description rejection of claims 1-2, 9, 19, and 27-38 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record.

RESPONSE TO ARGUMENT: Applicants argue a sufficient number of representative species has been disclosed, citing Table 14 as an example, to adequately describe all members of the genus.

Applicants' argument is not found persuasive. As stated in a previous Office action and supported by the prosecution history, the genus of claimed cutinase variants encompasses species that are widely variant in structure. In view of the recitation of the transitional phrase "comprising," the examiner has interpreted claims 1 and 28 as encompassing essentially any cutinase variant having mutations at positions corresponding to amino acids 192 and/or 194 of SEQ ID NO:2. The claims encompass widely variant species, including (but not necessarily limited to) any cutinase variant having any amino acid sequence from any source having mutations at positions corresponding to amino acids 192 and/or 194 of SEQ ID NO:2. In other words, the variant of claim, for example, is not limited to a SEQ ID NO:2 having mutations at positions 192 and/or 194. While variants of SEQ ID NO:2 having substitutions at positions 192 and/or 194 in addition to other mutations may be disclosed in the specification, the claims are not so limited. Applicants do not disagree with the examiner's broad interpretation of the claims (in accordance with MPEP 2111) and have

provided no reasoning as to why the examiner should not interpret the claims accordingly. At least for the reasons of record and the reasons stated herein, it is the examiner's position that these representative species fail to adequately describe the widely variant genus of cutinases as encompassed by the genus of the claims.

**[6]** The scope of enablement rejection of claim(s) 1-2, 9, 19, and 27-38 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record.

RESPONSE TO ARGUMENTS: Applicants assert the examiner has admitted the specification does not enable substitutions other than SEQ ID NO:2 having substitution at positions 192, 194, and/or 219. Applicants argue the specification enables the full scope of claimed cutinase variants.

In response to applicants' argument that the examiner has admitted the specification does not enable substitutions other than SEQ ID NO:2 having substitution at positions 192, 194, and/or 219, it is noted that applicants have mischaracterized the examiner's position. The examiner acknowledges that the specification and prior art enable cutinase variants other than SEQ ID NO:2 having substitution at positions 192, 194, and/or 219. However, applicants are reminded that the elected invention is drawn to a cutinase variant having mutation at positions 192, 194, and 219 of SEQ ID NO:2.

As stated above and in a previous Office action and supported by the prosecution history, the scope of claimed cutinase variants encompasses a broad scope of polypeptides. In view of the recitation of the transitional phrase "comprising," the examiner has interpreted claims 1 and 28 as encompassing essentially any cutinase variant having mutations at positions corresponding to amino acids 192 and/or 194 of

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SEQ ID NO:2. The claims encompass a broad scope of polypeptides, including (but not necessarily limited to) all cutinase variants having any amino acid sequence from any source having mutations at positions corresponding to amino acids 192 and/or 194 of SEQ ID NO:2. In other words, the variant of claim 1, for example, is not limited to SEQ ID NO:2 having mutations at positions 192 and/or 194. While variants of SEQ ID NO:2 having substitutions at positions 192 and/or 194 in addition to other mutations may be disclosed in the specification, the claims are not so limited. Applicants do not disagree with the examiner's broad interpretation of the claims (in accordance with MPEP 2111) and have provided no reason why the examiner should not interpret the claims accordingly. While the examiner acknowledges the disclosure of additional cutinase variants, at least for the reasons of record and the reasons stated herein, it is the examiner's position that the full scope of claimed cutinase variants fails to adequately describe the widely variant genus of cutinases as encompassed by the genus of the claims.

***Claim Rejections - 35 USC § 103***

**[7]** The rejection of claims 1-2, 9, and 27-38 under 35 U.S.C. 103(a) as being unpatentable over Poulouse et al. (US Patent 5,352,594; "Poulouse") is maintained for the reasons of record.

RESPONSE TO ARGUMENT: Applicants argue that during the development of the instant invention, the best-performing variants as described by Poulouse were insufficient to meet the need addressed in the present application. Applicants further

argue that Poulouse et al. teach mutations that increase perhydrolase activity and not mutations to increase polyesterase activity or enhance thermostability.

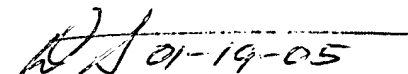
Applicants' argument is not found persuasive. It is noted that claims 1-2 and 31 are not limited to cutinase variants having increased polyesterase activity or enhanced thermostability. These variants are limited only to having polyesterase activity. Regarding those claimed cutinase variants that are limited to having increased polyesterase activity or enhanced thermostability, while it does not appear that Poulouse sought to achieve increased polyesterase activity or enhanced thermostability, according to MPEP 2144, "[i]t is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant." Poulouse clearly suggests mutating position 178 or 180 and optionally with mutation at position 205 of *P. mendocina* lipase (corresponding to position 192 or 194 and optionally with mutation at position 219 of SEQ ID NO:2 of the instant application), which is undisputed by applicants. MPEP 2112 states, "[t]he claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." In this case, it appears that applicants are claiming a new function for cutinase variants that were suggested by Poulouse at the time of the invention. At least for the reasons of record and the reasons stated herein, it is the examiner's position that the reference of Poulouse teaches or suggests all limitations of the claims, provides motivation for making the claimed cutinase variants, and provides a reasonable expectation of success for making the claimed cutinase variants.

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**[8]** Status of claims:

- Claims 1-2, 9, 19, and 27-38 are pending in the application.
- Claims 1-2, 9, 19, and 27-38 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

  
David J. Steadman, Ph.D.  
Primary Examiner  
Art Unit 1652

**DAVID J. STEADMAN, PH.D.**  
**PRIMARY EXAMINER**